



03-15-04

PTO/SB/92 (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application No. (if known): 10/719,534

Attorney Docket No.: 02591/100B206-US3

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Information Disclosure Statement (4pp)

Search Report issued in PCT/US97/07577 (3 pp)

Search Report issued in DP 97922668 (2 pp)

PTO/SB/08 (2 pp)

PTO/SB/92 Express Mail Certificate Under 37 CFR §1.10 (1 p)



Customer No.: 07278

Docket No.: 02591/100B206-US3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Anthony H. CINCOTTA et al.

Serial No.: 10/719,534

Art Unit: 1642

Filed: November 21, 2003

Examiner: Gary B. Nickol

For: **GROWTH INHIBITION AND ERADICATION OF SOLID TUMORS USING
NEUROENDOCRINE RESETTING THERAPY AND PHOTODYNAMIC
THERAPY**

March 12, 2004

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☐ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ C. Documents 1-53 on the attached PTO/SB/08 were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/187,768, filed November 6, 1998, and

Serial No. 08/838,079, filed April 15, 1997.

Copies of these documents need not be filed in this application. Applicant requests that these documents be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d).

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP ' 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP ' 609 A(3)).

[X] 5. Other information being provided for the examiner's consideration follows:

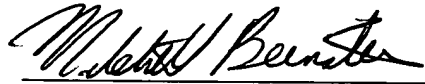
(A) An International Search Report, dated August 4, 1997, which issued during the prosecution of International Application No. PCT/US97/07577, which corresponds to the present application; and

(B) An international style Supplementary Search Report, dated October 15, 1999, which issued during the prosecution of European Application No. EP 97922668, which corresponds to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in '1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Mitchell Bernstein", is written over a horizontal line.

Mitchell Bernstein, Ph.D.
Registration No. 46,550
Agent for Applicant(s)

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PTO/SB/08a/b (06-03)

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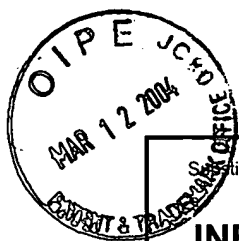
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/719,534
				Filing Date	November 21, 2003
				First Named Inventor	Anthony H. CINCOTTA
				Art Unit	1642
				Examiner Name	Gary B. NICKOL
Sheet	1	of	2	Attorney Docket Number	02591/100B206-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1.	3,752,814	08/14/1973	Fluckiger et al.	
	2.	3,752,888	08/14/1973	Fluckiger et al.	
	3.	5,225,433	07/06/1993	Dougherty et al.	
	4.	5,344,832	09/06/1994	Cincotta et al.	
	5.	5,468,755	11/21/1995	Cincotta et al.	
	6.	5,496,803	03/05/1996	Meier et al.	
	7.	5,554,623	09/10/1996	Cincotta et al.	
	8.	5,585,347	12/17/1996	Meier et al.	
	9.	5,792,748	06/1995	Cincotta et al.	
	10.	6,071,914	06/1995	Cincotta et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	11.	DE 3 216 869	11/03/1983			
	12.	DE 3 216 870	11/03/1983			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	13.	Lin, <i>Cancer Cells</i> 3: 437-444 (1991)	
	14.	Cincotta et al., <i>Cancer Res.</i> 54: 1249-1258 (1999)	
	15.	Lengyel et al., <i>Fert. & Steril.</i> 59: 980-987 (1993)	
	16.	Aldeghi et al., <i>Eur. J. Cancer</i> 30A:167-170 (1994)	
	17.	Barnett et al., <i>Postgrad. Med. J.</i> 56:11-14 (1980)	
	18.	Barni et al., <i>Oncology</i> 52:243-245 (1995)	
	19.	Bartsch et al., <i>J. Neural Transmission</i> 52:269-279 (1981)	
	20.	Bartsch et al., <i>Ann. NY Acad. Science</i> 719:502-525 (1994)	
	21.	Chatterjee et al., <i>Medline Abstract no.</i> 90095797 (1989)	
	22.	Cincotta et al., <i>Cancer Research</i> 54:1249-1258 (1999)	
	23.	Cos et al., <i>Medline Abstract no.</i> 95007479 (1994)	
	24.	Crespo et al., <i>Medline Abstract no.</i> 95106114 (1994)	
	25.	DiStefano et al., <i>Medline Abstract no.</i> 95239580 (1994)	
	26.	Furuya et al., <i>Medline Abstract no.</i> 94291081 (1994)	
	27.	Kane et al., <i>Medline Abstract no.</i> 94305357 (1994)	
	28.	Kikuchi et al., <i>Medline Abstract no.</i> 89079088 (1989)	
	29.	Lengyel et al., <i>Fertility and Sterility</i> 59:980-987 (1993)	

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/719,534
				Filing Date	November 21, 2003
				First Named Inventor	Anthony H. CINCOTTA
				Art Unit	1642
				Examiner Name	Gary B. NICKOL
Sheet	2	of	2	Attorney Docket Number	02591/100B206-US3

30.	Leone et al., <i>J. Pineal Res.</i> 17:17-19 (1994)	
31.	Lin, <i>Cancer Cells</i> 3:437-444 (1991)	
32.	Lissoni et al., <i>Medline Abstract no.</i> 90229655 (1990)	
33.	Lissoni et al., <i>Medline Abstract no.</i> 94225687 (1993)	
34.	Lissoni et al., <i>Medline Abstract no.</i> 89289750 (1989)	
35.	Lissoni et al., <i>Oncology</i> 49:336-339 (1992)	
36.	Lissoni et al., <i>Cancer</i> 73:699-701 (1994)	
37.	Lissoni et al., <i>Oncology</i> 51:344-347 (1994)	
38.	Lissoni et al., <i>Oncology</i> 52:163-166 (1995)	
39.	Lissoni et al., <i>British J. of Cancer</i> 71:854-856 (1995)	
40.	Maestroni et al., <i>Medline Abstract no.</i> 94340606 (1994)	
41.	Meier et al., <i>Experientia</i> 48:248-253 (1992)	
42.	Neri et al., <i>Cancer</i> 73:3015-3019 (1994)	
43.	Redman et al., <i>Science</i> 219:1089-1091 (1983)	
44.	Regelson et al., <i>Cancer Investigation</i> 5:379-385 (1987)	
45.	Wauldhaser et al., <i>Melatonin in Human Body Fluids: Clinical Significance:</i> 345-363	
46.	Werning et al., <i>Arch. Otolaryngol. Head Neck Surg.</i> 121:783-789 (1995)	
47.	Coppola, A et al., "Augmentation of Photodynamic Effects: The Synergistic Action of Hematoporphyrin and Chlorpromazine," <i>J. Tumor Marker Oncol.</i> 1(3):205-211 (1986)	
48.	Cincotta, L. et al., "Novel Red Absorbing Benzo[a]phenoxazinium and Benzo[a]phenothiazinium Photosensitizers: In Vitro Evaluation," <i>Photochem. Photobiol.</i> 46(5):751-758 (1987)	
49.	Cincotta, L. et al., "Phototoxicity, Redox Behavior, and Pharmacokinetics of Benzophenoxazine Analogues in EMT-6 Murine Sarcoma Cells," <i>Cancer Research</i> 53(11):2571-2580 (1993)	
50.	Molitch, M.E., <i>Endocrinol. Metab. Clin. North Am.</i> 21(4) (1992) (abstract only)	
51.	Cincotta et al., <i>Cancer Research</i> 53:2571-2579 (1993)	
52.	Nagasawa et al., <i>Cancer Research</i> 34:2643-2646 (1974)	
53.	Bergh et al., <i>N. Engl. J. Med.</i> 300(24) (1979) (abstract only)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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